

Docket No.: 50179-101

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of

Ian L. BROWN, et al.

Serial No.: Divisional of Appln. Serial No. 09/155,116

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Group Art Unit: To be assigned

Filed: February 12, 2002

Examiner: To be assigned

For: ALTERATION OF MICROBIAL POPULATIONS IN THE GASTROINTESTINAL TRACT

**PRELIMINARY AMENDMENT**

Commissioner for Patents  
Washington, DC 20231

Sir:

Prior to examination of the above-referenced application, please amend the application as follows:

IN THE SPECIFICATION:

On page 1, after the title, please insert the following:

--CROSS-REFERENCE TO RELATED APPLICATION:

This application is a Divisional of U.S. Application Serial No. 09/155,116, filed on January 29, 1999, which is a 371 of PCT/AU97/00174, filed March 20, 1997.--.

IN THE CLAIMS:

Please replace claims 5, 22, 24 - 27 and 30 - 31 as follows:

5. The method according to claim 3 wherein the resistant starch is selected from high

amylose starches and modified forms thereof.

22. The improved probiotic composition according to claim 20 wherein the high amylose starch includes maize starch having an amylose content of 50% w/w or more.

24. The improved probiotic composition according to claim 20 wherein the high amylose starch includes rice or wheat starch having an amylose content of 27% w/w or more.

25. The improved probiotic composition according to claim 20 wherein the high amylose starch includes a particular granular size ranges of starches having an amylose content of 50% or more with enhanced resistant starch content.

26. The improved probiotic composition according to claim 20 wherein the high amylose starch is derived from plants selected from the group consisting of maize, barley, wheat, rice, legumes, bananas, potatoes, or modified forms thereof.

27. The improved probiotic composition according to claim 20 wherein the resistant starch is modified chemically, enzymatically, and/or physically.

30. The improved probiotic composition according to claim 20 wherein the modified resistant starch is selected from the group consisting of hydroxypropylated starch, acetylated starch, octenyl succinated starch, carboxymethylated starch, and succinated starch.

31. An improved method of providing probiotic microorganisms to the gastrointestinal tract of an animal, the improved method comprising administering to the animal the improved probiotic composition according to claim 20.

IN THE DRAWINGS:

Please insert the substitute sheets of drawings, figures 1-15, for the drawings as originally filed.

REMARKS

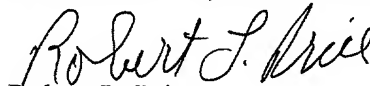
The above amendment has been made to eliminate multiple dependency of claims 5, 22, 24 - 27 and 30-31. In addition, the amendment incorporates the information on related applications.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Entry of this amendment is respectfully requested.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

5. (Amended) The method according to claim 3 [or 4] wherein the resistant starch is selected from high amylose starches and modified forms thereof.

22. (Amended) The improved probiotic composition according to claim 20 [or 21] wherein the high amylose starch includes maize starch having an amylose content of 50% w/w or more.

24. (Amended) The improved probiotic composition according to claim 20 [or 21] wherein the high amylose starch includes rice or wheat starch having an amylose content of 27% w/w or more.

25. (Amended) The improved probiotic composition according to claim 20 [or 21] wherein the high amylose starch includes a particular granular size ranges of starches having an amylose content of 50% or more with enhanced resistant starch content.

26. (Amended) The improved probiotic composition according to claim 20 [or 21] wherein the high amylose starch is derived from plants selected from the group consisting of maize, barley, wheat, rice, legumes, bananas, potatoes, or modified forms thereof.

27. (Amended) The improved probiotic composition according to [any one of claims 20 to 26] claim 20 wherein the resistant starch is modified chemically, enzymatically, and/or physically.

30. (Amended) The improved probiotic composition according to [any one of claims 20 to 26] claim 20 wherein the modified resistant starch is selected from the group consisting of

hydroxypropylated starch, acetylated starch, octenyl succinated starch, carboxymethylated starch, and succinated starch.

31. (Amended) An improved method of providing probiotic microorganisms to the gastrointestinal tract of an animal, the improved method comprising administering to the animal the improved probiotic composition according to [any one of claims 20 to 30] claim 20.

WDC99 557662-1.050179.0101

## CLAIMS:

1. A method of enhancing a resident population of microorganism in a selected site of the gastrointestinal tract of an animal, the method comprising providing to the animal a selected modified or unmodified resistant starch in the form of high amylose starches or mixtures thereof in combination with one or more probiotic microorganisms such that upon ingestion the starch passes through the gastrointestinal tract substantially unutilized until it reaches the selected site where it is utilised by the resident and/or the probiotic microorganisms thereof causing an increase in number and/or activity of the microorganisms.

2. A method of suppressing an undesired resident population of microorganism in a selected site of the gastrointestinal tract of an animal, the method comprising providing to the animal a modified or unmodified resistant starch in the form of high amylose starches or mixtures thereof in combination with one or more probiotic microorganisms such that upon ingestion the starch passes through the gastrointestinal tract substantially unutilized until it reaches the selected site where it is utilised by another resident and/or the probiotic microorganisms causing an increase in number and/or activity of the other microorganisms and suppressing the growth and/or activity of the undesired microorganism.

3. A method of reducing the incidence colorectal cancer or colonic atrophy in an animal, the method comprising providing to the animal one or more short chain fatty acid (SCFA) producing probiotic microorganisms and a carrier which will function to transport the one or more probiotic microorganisms to the large bowel or other regions of the gastrointestinal tract, the carrier comprising a modified or unmodified resistant starch or mixtures thereof, which carrier acts as a growth or maintenance medium for microorganisms in the large bowel or other regions of the gastrointestinal tract so as to enhance SCFA production by probiotic and/or resident microorganisms in the gastrointestinal tract of the animal.

4. The method according to claim 3 wherein the SCFA is butyrate and the probiotic and/or microorganisms in the gastrointestinal tract are *Cl. butyricum* and/or *Eubacterium*.

5. The method according to claim 3 or 4 wherein the resistant starch is selected from high amylose starches and modified forms thereof.

6. The method according to any one of claims 1, 2 or 5 wherein the high amylose starch includes maize starch having an amylose content of 50% w/w or more.
7. The method according to claim 6 wherein the maize starch having an amylose content of 80% w/w or more.
8. The method according to any one of claims 1, 2 or 5 wherein the high amylose starch includes rice or wheat starch having an amylose content of 27% w/w or more.
9. The method according to any one of claims 1, 2 or 5 wherein the high amylose starch includes particular granular size ranges of starches having an amylose content of 50% or more with enhanced resistant starch content.
10. The method according any one of claims 1, 2 or 5 wherein the high amylose starch is derived from plants selected from the group consisting of maize, barley, wheat, rice, legumes, bananas, potatoes, and modified forms thereof.
11. The method according to any one of claims 1 to 10 wherein the resistant starch is modified chemically, enzymatically, and/or physically.
12. The method according to claim 11 wherein the chemical modification is by cross-bonding, etherification, esterification, or acidification.
13. The method according to claim 11 wherein the physical modification is by crystallisation.
14. The method according to any one of claims 1 to 10 wherein the modified resistant starch is selected from the group consisting of hydroxypropylated starch, acetylated starch, octenyl succinated starch, carboxymethylated starch, and succinated starch.
15. The method according to any one of claims 1 to 14 wherein the growth and/or activity of the resident microorganisms is increased.
16. The method according to any one of claims 1 or 14 wherein the growth and/or activity of the probiotic microorganisms is increased.
17. The method according to any one of claims 15 or 16 wherein the selected site is the small intestine, stomach, or large bowel.
18. The method according to claim 2 wherein the undesired resident microorganism is a microbial pathogen.

19. The method according to claim 18 wherein the resistant starch acts as a carrier which will function to transport the one or more probiotic microorganisms to the selected site of the gastrointestinal tract, and which carrier acts as a growth or maintenance medium for the non-pathogenic microorganisms in the selected site of the gastrointestinal tract to an extent sufficient to suppress growth and/or activity of the microbial pathogen.

20. An improved probiotic composition comprising one or more probiotic microorganisms and a carrier which will function to transport the one or more probiotic microorganisms to the large bowel or other regions of the gastrointestinal tract, the carrier comprising modified or unmodified resistant starch in the form of high amylose starches or mixtures thereof to which the probiotic microorganisms are bound in a manner so as to protect the microorganisms during passage to the large bowel or other regions of the gastrointestinal tract, which carrier acts as a growth or maintenance medium for microorganisms in the large bowel or other regions of the gastrointestinal tract.

21. The improved probiotic composition according to claim 20 wherein the probiotic microorganisms are bound irreversibly to the resistant starch.

22. The improved probiotic composition according to claim 20 or 21 wherein the high amylose starch includes maize starch having an amylose content of 50% w/w or more.

23. The improved probiotic composition according to claim 22 wherein the maize starch having an amylose content of 80% w/w or more.

24. The improved probiotic composition according to claim 20 or 21 wherein the high amylose starch includes rice or wheat starch having an amylose content of 27% w/w or more.

25. The improved probiotic composition according to claim 20 or 21 wherein the high amylose starch includes particular granular size ranges of starches having an amylose content of 50% or more with enhanced resistant starch content.

26. The improved probiotic composition according to claim 20 or 21 wherein the high amylose starch is derived from plants selected from the group consisting of maize, barley, wheat, rice, legumes, bananas, potatoes, and modified forms thereof.



27. The improved probiotic composition according to any one of claims 20 to 26 wherein the resistant starch is modified chemically, enzymatically, and/or physically.

5 28. The improved probiotic composition according to claim 27 wherein the chemical modification is by cross-bonding, etherification, esterification, or acidification.

29. The improved probiotic composition according to claim 27 wherein the physical modification is by crystallisation.

10 30. The improved probiotic composition according to any one of claims 20 to 26 wherein the modified resistant starch is selected from the group consisting of hydroxypropylated starch, acetylated starch, octenyl succinated starch, carboxymethylated starch, and succinated starch.

15 31. An improved method of providing probiotic microorganisms to the gastrointestinal tract of an animal, the improved method comprising administering to the animal the improved probiotic composition according to any one of claims 20 to 30.